RAJYA SABHA

Tuesday, the 29th November, 1988/8th Agrahayana, 1910 (Saka)

The House met at eleven of the clock, **Mr. Chairman** in the Chair.

MEMBERS SWORN

Shri Bir Bahadur Singh (Uttar Pradesh)

ORAL ANSWERS TO QUESTIONS

Drug Control Enforcement in the North Eastern States

*241. DR. G. VIJAYA MOHAN REDDY:†

SHRI BHAGATRAM MANHAR:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there is hardly any Drug Control Enforcement machinery in the North Eastern States;

(b) if so, what is its present set up and what is its total strength and how it compares in this regard with that in the other States;

(c) what are the findings in this regard in the Report of the WHO Drug Consultant; and

(d) what steps Government propose to take to remedy the situation?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) There are 7 Drug Controllers, 2 Deputy Drug Controllers, one Assistant Drug Controller and 30 Drug Inspectors in the seven North-Eastern States.

As per the norms laid down for determining posts in the Drug Inspectorate, the set up in several States including the North-Eastern States needs improvement.

(c) and (d) The WHO Drug Consultant has *inter-alia* recommended augmentation of the Inspectorate in the North-Eastern States and the establishment of a combined Drug Testing laboratory for all North-Eastern States so that more samples can be drawn from the drugs available and their quality could be assessed expeditiously.

The recommendations have been brought to the notice of the concerned State Government for implementation.

As regards the setting up of Drug testing laboratories, the North-Eastern Council has already sponsored the setting up of Food and Drug Laboratories, one each, in Meghalaya and Tripura besides augmenting existing facilities at Guwahati, during the Seventh Plan period, The schemes are under implementation and likely to be completed by March, 1990.

DR. G. VIJAYA MOHAN REDDY: Mr. Chairman Sir, to protect the health of the nation, it is necessary for the Government to have a drug policy which would ensure self-reliance is production and distribution of essential and other drugs at a cheap rate with strict quality control. None of these policies is served by the present drug policy which has given a free hand to multinational drug companies to penetrate. And with 8,000 manufacturers and 50,000 to 60,000, formulations under brand names. It is beyond anybody's imagination for any quality control or standardisation. Some of the banned drugs are pushed into the market and drugs are being sold at higher costs than prescribed by the Government and practically there is no action against those who flout the rule. The Hon. Minister in one of the replies had stated that from the

†The question was actually asked on the floor of the House by Dr. G. Vijaya Mohan Reddy.

analysis of the samples received by the drug testing laboratories, as many as 15 to 18 per cent were found to be sub-standard. With only 5 laboratories qualified to test drugs and not having enough of Drug Inspectors to collect the samples, it is right conjectured that 30 per cent of the drugs and vaccines manufactured are substandard, sometimes downright spurious and dangerous, which are affecting the health of the nation, immunisation programmes and also medical care by the hospitals. Under these conditions when drug production is reaching a figure of Rs. 3,700 crores, will the Government change the present policy, which is not at all serving the people and see that cheap essential drugs and other vaccines are manufactured under generic names and not under brand names, and there are not more than five to six hundred drugs which will be completely sufficient as in any other developed country and the guidelines of the WHO in this direction are implemented? Will the drug companies be made to contribute...

MR. CHAIRMAN: Will you put your question?

DR. G. VIJAYA MOHAN REDDY: ...a percentage of their profits for quality control of the drugs?

KUMARI SAROJ KHAPARDE: So, the hon. Member is asking something not related to the question. For these kinds of supplementaries I need separate notice. The question relates to the North-Eastern region.

DR. G. VIJAYA MOHAN REDDY: I am trying to say that the reply given previously by the Minister...

MR. CHAIRMAN: The question is very simple, whether you will make the drug manufacturers bear the burden...

DR. G. VIJAYA MOHAN REDDY: Are you going to change the drug policy which is not at all serving the people?

MR. CHAIRMAN: You only answer his question, that is the last part, as he has said. That is all.

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): Sir, the hon. Member has given a number of suggestions also and the question is related to the North-Eastern Region, where we have got about 51 manufacturing units. These samples have always been tested there and if they are found spurious action has been taken. So, whatever the hon. Member has said, his suggestions are really valuable. We will look into them as and when the necessity arises.

DR. G. VIJAYA MOHAN REDDY: Sir, my second supplementary is that I want to submit that the Central Government has taken concurrent powers under the Drug Amendment Act, 1964, and 24 years have passed after these powers have been taken.

MR. CHAIRMAN: You come to your question.

DR. G. VIJAYA MOHAN REDDY: The hon. Minister has said that there are seven drug controllers, two deputy drug controllers and thirty drug inspectors. He has accepted...

MR. CHAIRMAN: He has accepted the inadequacy.

DR. G. VIJAYA MOHAN REDDY: The Minister has not said whether these are full time qualified drug controllers...

MR. CHAIRMAN: You want to know whether they are full time or part-time.

DR. G. VIJAYA MOHAN REDDY: Yes, but there is something more than that also.

MR. CHAIRMAN: Then you ask that.

DR. G. VIJAYA MOHAN REDDY: The hon. Minister has not stated about the financial assistance When they have taken concurrent powers, what is

the financial assistance the Government of India wants to provide, so that the drug testing laboratory is situated...

MR. CHAIRMAN: You want to know whether they are giving any financial assistance. Are you giving any financial assistance?

SHRI MOTI LAL VORA: Sir, number one is that these drug controllers are actually not fulltime, as the hon. Member has said, the Directors of Health Services are acting drug controllers under the North-Eastern Region. As far as the finances are concerned, the North-Eastern Council have provided finance for the setting up of laboratories and whatever funds are needed, those are being provided by the Government of India through the North-Eastern Council.

DR. G. VIJAYA MOHAN REDDY: It is affecting the health of the people.

MR. CHAIRMAN: You have already put two questions. Now, Mr. Manhar.

SHRI BHAGATRAM MANHAR: Mr. Chairman, Sir, from the reply of the hon. Minister, it appears that the position of enforcement of drug control law in the North-Eastern States is not only very poor but pathetic. It reflects on the negligence of this sensitive area in the last 41 years, since the drug control law was enacted. Sir, you will agree that the North-Eastern States are very sensitive and vulnerable. They have become a dumping ground of all sub-standard, rejected and time expired drugs. I would therefore like to know from the Government as to what comprehensive action is proposed to be taken to eliminate these evils from the North-Eastern States. Part (b) of my question is that the Central Government took the power under the Drug Control Act in 1964. Yet, so far the Central Government has not done anything to save the people from the use of these spurious and sub-standard drugs. I do not know whether any representation has been received from the administration of these States in the matter. One of the reasons for making the whole of North Eastern India into a vast empire of unscrupulous people...

MR. CHAIRMAN: Come to your supplementary.

SHRI BHAGATRAM MANHAR: I am coming to that. There is no machinery to treat the drug samples. The manufacturers and the dealers take full advantage of this lacuna. I would, therefore, like to know whether the Government will immediately arrange for taking at least one thousand drug samples from these States into the Calcutta laboratory without charging any fees because presently they have to pay for sample testing. Calcutta laboratory sometimes does not even test the samples and whatever samples are drawn, there is delay of 8 to 10 months in testing. I, therefore, want to know whether Calcutta laboratory will be strengthened for the purpose, and also whether any drug laboratory is proposed to be set up in any of the North-Eastern States to control this menace.

SHRI MOTI LAL VORA: The supplementary is just like a full main question. Anyway, the hon. Member has said that the number of drug inspectors is insufficient against whatever facilities we have provided in the seven States of the North-Eastern region. We have got 30 drug inspectors against the total number of 676 for the whole country. The number of manufacturing premises is 51 in the North-Eastern region and the number of sales premises in North-Eastern region is 4934. So, for meeting this number of sales premises the number of inspectors in North-Eastern region is not insufficient. If we compare it to the national average. The national average is 1 against 23 whereas in the North-Eastern region, it comes to 1.7 against one. Regarding testing, the North-Eastern Council had made suggestions and some funds have been provided for the purpose in the Seventh Five-Year Plan. They are going

to have one such facility at Shillong and also at Tripura. In Assam also, at Guwahati, they have got their old testing laboratory and that is being expanded in the Seventh Five-Year Plan. A provision of Rs. 87 lakhs has been made. Whatever testing is needed, they are getting it done in Calcutta. Sometimes samples are being sent to Ghaziabad also. Then there is a third laboratory at Madras. So as and when they want, samples are being sent to various laboratories.

SHRI KAMALENDU BHATTACHARJEE: Is the hon. Minister aware that in the Silchar town of Assam, about 19 persons expired after taking an injection which is supposed to prevent hydrophobia caused by dog-bite? May I know what steps are being taken to prevent occurrence of such incidents?

SHRI MOTI LAL VORA: The question does not relate to the main question but since the hon. Member...

MR. CHAIRMAN: People may have died in the North-Eastern region.

SHRI MOTI LAL VORA: I said the question is about dog bite.

MR CHAIRMAN: You can have it investigated.

SHRI MOTI LAL VORA: Yes, we will have it investigated and if any vaccine is required there, we will definitely supply.

MR. CHAIRMAN: If the vaccine is defective and resulted in deaths, it has to be investigated.

SHRI MOTI LAL VORA: Since the hon. Member has invited our attention to it, we will enquire into the whole matter, because 19 persons have died; it is not a small thing.

डा० रत्नाकर पाण्डेय : माननीय सभापति जी, इस समय देश के अधिकांश भागों में, गांवों और देहातों की बात छोड़ दी जाए, शहरों में भी खुले आम टाइम बारड दवाइयों को बेचा जा रहा है।

श्री सभापति : आप सिर्फ नार्थ ईस्ट पर ही रहिए।

डा० रत्नाकर पाण्डेय : 260 नम्बर प्रश्न जो है वह इसी से संबंधित है।

श्री सभापति : नहीं-नहीं, आप केवल इसी सवाल पर रहिए।

डा० रत्नाकर पाण्डेय : मैं आपके माध्यम से नार्थ ईस्ट जोन के संदर्भ में जानना चाहूंगा कि दवाइयों के जो सैंपल हैं, उनको लेबोरेटरी में टेस्ट करवाया जाता है और उनके नकली साबित होने पर क्या सरकार के पास कोई शक्ति है कि नकली दवाइयां बनाने वालों के खिलाफ कड़ा कदम उठाया जा सके। अध्यक्ष महोदय, जस्टिस लेण्टिन ने अभी एक रिपोर्ट प्रस्तुत की है, उससे क्या मंत्री महोदय परिचित है ? अगर यह रिपोर्ट मंत्रालय के ध्यान में आई है तो जस्टिस लेण्टिन की सिफारिशों पर क्या प्रभावी कदम उठाए जा रहे हैं ? दूसरा, मंत्री महोदय से मैं यह जानना चाहूंगा कि सब स्टेण्डड ड्रग्स, मिलावटी दवाइयों के जो मामले इस वर्ष सामने आए हैं, उनमें कितनों के खिलाफ कानूनी कार्यवाही की गई है ?

श्री सभापति : नार्थ-ईस्ट में ?

डा० रत्नाकर पाण्डेय : नॉर्थ-ईस्ट से ही मेरा सवाल है। साथ ही ड्रग्स कंट्रोल एक्ट में क्या कोई संशोधन करने का विचार मंत्रालय रखता है ?

श्री मोती लाल वोरा : माननीय सभापति महोदय, माननीय सदस्य ने नार्थ ईस्ट रीजन के बारे में पूछा कि जो सबस्टेंडर्ड की दवाइयां वहां पाई गई, उस पर क्या कार्यवाही की गई, मैं माननीय सदस्य को बताना चाहता हूं कि 1982-83, 83-84, 84-85 85-86 और 86-87 में ही एक प्रश्न लेकर देखा तो 288 सैम्पल की टेस्टिंग हुई, उसमें से 269 सैंपल सही पाए गए और सब स्टेंडर्ड पाए गए 19,

और इस पर कार्यवाही राज्य सरकार वहां पर करती है, इस पर प्रोसीक्यूशन भी होते हैं । जहां तक स्पूरियस ड्रग्स का सवाल है, असम में इस अवधि मे कोई स्पूरियस ड्रग्स नही पाए गए, 1986-87 में जो स्पूरियस ड्रग्स पाए गए, जैसी माननीय सदस्य ने चिंता व्यक्त की है । नार्थ ईस्ट रीजन में इस प्रकार की घटिया किस्म की दवाइयां या मिलावटी दवाइयां जहां ध्यान में आई हैं, राज्य सरकार वहां उन पर कार्यवाही कर रही है और कुछ केस माननीय न्यायालय में भी, अध्यक्ष महोदय, भेजे गए हैं ।

DR. (SHRIMATI) SAROJINI MAHISHI: Sir, the Drug Control Act was passed in 1940. Rules were framed in 1945. Enforcement started in 1947. Forty-one years have passed. What is the progress we have been able to achieve? In the testing of the spurious drugs which are sent to the laboratories, there is a lot of delay and, therefore, we are not able to get the results in time. This means action also can not be taken in time. This should have come to the notice of the hon. Minister. This has become a dumping ground for all the discarded area, vaccine and other spurious drugs. In the larger interest of the consumers who make use of these drugs, in 1964, this came under the Concurrent List. But I would like to know what has been done in the last twenty-four years when it has been on the Concurrent List. How many laboratories have been established for the purpose of expediting the analytical reports in regard to the spurious drugs? This is the main thing I wanted to know. What is the infrastructure which has ben built by the Central Government under the concurrent powers which they got in 1964?

SHRI MOTI LAL VORA: Sir, the Government has the power to suspend the licence if the drug is found substandard, as I have mentioned. The Government has the power. The amended Drugs and Cosmetics Act, 1982 gives the power to the licensing authority to take action with regard to the drugs which are found spurious. Generally, we ask the State Governments for information. They take some time for taking all these actions. After that, cases are sent to the courts for prosecution. This is the only remedy.

But Sir, as the hon. Member said, we will ask the State Governments, the Drug Controllers in the States, to expedite these cases which have been lying for a number of years. If no action had been taken, we will ask them why no action had been taken. We will definitely ask the State Governments in this regard.

DR. (SHRIMATI) SAROJINI MAHISHI: Can the hon. Minister give the number of cases which have been pending for the last one decade or more without any prosecution?

SHRI MOTI LAL VORA: Sir, I think this requires notice because the main question relates to the North-Eastern Region. There is no such case pending. Two cases have been filed and prosecutions have started in the North-Eastern Region.

SHRI DHARANIDHAR BASUMATARI: Sir, in the course of his reply the hon. Minister has stated that the Centre has also the powers. I know the inefficiency of the State Government. The condition there has deteriorated. I want to ask whether the Centre is doing something, whether they are extending all help to the State Government, whether they will see that the affairs are managed efficiently.

SHRI MOTI LAL VORA: The condition has not deteriorated in the North-Eastern region because there is no such information. Generally we get information from the State Governments. Sometimes we send our own Drug Inspectors who supervise the samples, see them and then send the information through State Governments.

SHRI G. SWAMINATHAN: Sir, pharmaceutical industry is a specialised subject and so it is controlled by Drug Controllers. The Hathi Committee recommended that professional people should be appointed as Drug Controllers and not the doctors as Director of Medical Education, Medical Services or Preventive Medicines. Still these people are appointed in many of the States. Is the hon. Minister aware that because of want of appointment of the professional people as Drug Controllers in many States, especially in these States, it is hampering the progress of the Drug Controller's administration? Another thing is corruption. There is a nexus between the Drug Controller department the manufacturers and the chemists who are selling these drugs. Justice Lentin Committee has amply brought this out in Maharashtra and it is going about in many other places, especially in these States. As far as I could understand this is the area where corruption should be averted because it is playing with the lives of the people. Will the Government take special monitoring efforts to see that there is no corruption from top to bottom on the side of the officials? Will you take specific action against the people who are manufacturing spurious and substandard drugs because it is playing with the lives of the people?

SHRI MOTI LAL VORA: As far as the report of Justice Lentin Committee is concerned, we have circulated it to all the State Governments earlier and we have requested them to take action accordingly. I have written letters to all the Chief Ministers just after the report of Justice Lentin Committee was received.

About the drugs which are taking the lives of the people in North-Eastern region or any part of the country, I may humbly say that I have no information about the North-Eastern region. Since the hon. Member is saying all this we will take note of the same because this is a very serious thing. We will get information from the State Governments very soon so that we are acquainted with the information about Controllers in the States, what they are doing, what is the number of deaths there because of these spurious drugs and the drugs which are not used for human consumption. We will get the information and let the hon. Member know.

SHRI G. SWAMINATHAN: What about appointment of professional people?

MR. CHAIRMAN: He wants to know about the appointment of those who are professionally qualified.

SHRI MOTI LAL VORA: We will examine this. It is a good suggestion, we will examine it.

SHRI JAGESH DESAI: It has come to the knowledge of the Minister that there are many testing laboratories who certify substandard drugs also as consumable drugs. I want to know whether any case has been found in respect of North-Eastern region and if so, what action has been taken by the Government.

SHRI MOTI LAL VORA: The testing laboratory is in Calcutta and in Gauhati.

MR. CHAIRMAN: Gauhati is in the North-Eastern region.

SHRI MOTI LAL VORA: Yes, he is asking about the North-Eastern region. Sometimes we send a number of cases to Calcutta also. We are equipping this Gauhati laboratory properly. A sum of Rs. 18 lakhs is being provided this year to equip this Gauhati laboratory. Samples will be tested properly there.

MR. CHAIRMAN: Next Question.